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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,534	06/01/2006	Christopher John Burns	415852000200	6170

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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
WILLIS, DOUGLAS M	
ART UNIT	**PAPER NUMBER**
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,534	BURNS ET AL.	
	Examiner	Art Unit	
	DOUGLAS M. WILLIS	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12 and 14-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims / Priority

Claims 1-12 and 14-20 are pending in the current application. According to the *Amendments to the Claims*, filed June 1, 2006, claims 2-6, 9, 11, 12, 14, 15 and 17-20 were amended and claim 13 was cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2003/001661, filed December 11, 2003, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/483,399, filed June 26, 2003.

Restrictions

Restriction is required under 35 U.S.C. § 121 and § 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 5, 6, 12 and 14, is drawn to substituted pyrazines and pharmaceutical compositions of the formula II.

NOTE: *Claims 5 and 14 are generic to Group I. If Group I is elected, applicant must elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted pyrazine or pharmaceutical composition of the formula I, including a detailed explanation of how all variables of the formula I are read upon and what claims are readable upon the species.*

Group II, claims 7-9, 12 and 14, is drawn to substituted pyrimidines and pharmaceutical compositions of the formula III or formula IV, where X_1 = -C-; X_2 = -N-; X_3 = -C-; and X_4 = -N- or X_1 = -N-; X_2 = -N-; X_3 = -C-; and X_4 = -C-.

NOTE: *Claims 7 and 14 are generic to Group II. If Group II is elected, applicant must*

elect a provisional species, ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted pyrimidine or pharmaceutical composition of the formula III or formula IV, including a detailed explanation of how all variables of the formula III or formula IV are read upon and what claims are readable upon the species.*

Group III, claims 10, 11 and 14, is drawn to substituted 1,2,4-triazines and pharmaceutical compositions of the formula V, where X_1 = -N-; X_2 = -C-; X_3 = -N-; and X_4 = -N-.

NOTE: *Claims 10 and 14 are generic to Group III. If Group III is elected, applicant must elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted 1,2,4-triazine or pharmaceutical composition of the formula V, including a detailed explanation of how all variables of the formula V are read upon and what claims are readable upon the species.*

Group IV, claims 7-10 and 14, is drawn to substituted heteroaryls and pharmaceutical compositions of the formula…, where the combination of X_1, X_2, X_3 and X_4, as recited, is not as defined above.

NOTE: *Claims 7 or 10 and 14 are generic to Group IV. If Group I is elected, applicant must elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted heteroaryl or pharmaceutical composition of the formula…, including a detailed explanation of how all variables of the formula… are read upon and what claims are readable upon the species. Also, scope is restricted to and claims readable will accurately be determined for Group IV, once defined.*

Group V, claims 1-4, is drawn to a method of modulating microtubule polymerization in a subject, comprising administering… a substituted pyrazine of the formula I.

NOTE: *Claim 1 is generic to Group V. If Group V is elected, applicant must elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted pyrazine of the formula I, including a detailed explanation of how all variables of the formula I are read upon and what claims are readable upon the species.*

Group VI, claims 15-17, is drawn to a method of treatment of a hyperproliferation-related disorder or disease state in a subject…, comprising administering… a substituted heteroaryl of the formula….

NOTE: *Claim 15 is generic to Group VI. If Group VI is elected, applicant must elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted heteroaryl of the formula…, including a detailed explanation of how all variables of the formula… are read upon and what claims are readable upon the species. Also, scope is restricted to: a) a particular disease or disorder, selected from*

those recited in claim 17; and b) one of the compound groups listed as Groups I-IV above.

Group VII, claims 18 and 19, is drawn to a method of treatment of a protein-kinase related disorder or disease in a subject, comprising administering… a substituted heteroaryl of the formula….

NOTE: *Claim 18 is generic to Group VII. If Group VII is elected, applicant must elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted heteroaryl of the formula…, including a detailed explanation of how all variables of the formula… are read upon and what claims are readable upon the species. Also, scope is restricted to: a) a particular disease or disorder, selected from those recited in claim 19; and b) one of the compound groups listed as Groups I-IV above.*

Group VIII, claim 20, is drawn to a method of treatment of diseases and conditions associated with inflammation and infection in a subject, comprising administering… a substituted heteroaryl of the formula….

NOTE: *Claim 20 is generic to Group VIII. If Group VIII is elected, applicant must elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *clearly identifying a substituted heteroaryl of the formula…, including a detailed explanation of how all variables of the formula… are read upon and what claims are readable upon the species. Also, scope is restricted to: a) a particular disease or disorder associated with inflammation and infection; and b) one of the compound groups listed as Groups I-IV above.*

NOTE: *The examiner has interpreted claim 14 as a simple composition containing a compound. Consequently, if any one of Groups I-IV is elected, claim 14* ***must*** *be amended or cancelled to accurately reflect such an election or association.*

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), *the international application shall relate to one invention only or to a group of inventions*. Moreover, as stated in PCT Rule 13.2, the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled *where a group of inventions is claimed in one and the same international application only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features*. The expression *special technical features* shall mean those technical features that define a contribution which each of the claimed

inventions, considered as a whole, makes over the prior art, so linked, as to form a single general inventive concept.

The inventions listed as Groups I-VIII lack a *special technical feature*. Moreover, the inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding *special technical feature* for the following reason: *WO 03/099796*, cited in the international search report, teaches substituted pyrazines of the formula I as protein kinase inhibitors [p. 55, example 35]. Consequently, the inventions listed as Groups I-VIII do not share a *special technical feature* and do not relate to a single general inventive concept under PCT Rule 13.1.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are listed above in *Restrictions*.

The claims are deemed to correspond to the species listed above in the following manner:

Group I - claims 6 and 12; Group II - claims 8, 9 and 12; Group III - claim 11; Group IV - claims 8 and 9; Group V - claims 2-4; Group VI - claims 16 and 17; Group VII - claim 19; and Group VIII - claim 20.

The following claims are generic:

Group I - claims 5 and 14; Group II - claims 7 and 14; Group III - claims 10 and 14;

Group IV - claims 7 or 10 and 14; Group V - claim 1; Group VI - claim 15; Group VII - claim 18; and Group VIII - claim 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding *special technical feature* for the following reason: *WO 03/099796*, cited in the international search report, teaches substituted pyrazines of the formula I as protein kinase inhibitors [p. 55, example 35].

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. § 101 and/or 35 U.S.C. § 112, first paragraph.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Applicant is required, in reply to this action, to elect a single species, ***for searching purposes and prosecution on the merits only***, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include: **(i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143)** and **(ii) identification of the claims encompassing the elected invention.**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, AU 1624